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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,053	09/28/2000	James Oliver Dolly	17044DIV1 (AP)	2480

7590 06/10/2005

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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 06/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/676,053	DOLLY ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31,32 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,32 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/750,101.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9-28-00 + 11-6-00*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

8.0-01

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV in the reply filed on 12-23-2003 is acknowledged. The traversal is on the ground(s) that the Examiner has not demonstrated that the various inventions are separate and distinct nor has the Examiner demonstrated an increased search burden. This is not found persuasive because cancellation of all claims not drawn to the subject matter of the elected group has rendered the traversal moot.

The requirement is still deemed proper and is therefore made FINAL.

The amendment filed on 4-4-2005 is acknowledged. Claims 31-32 and 34 have been amended. Claims 21-30 and 33 have been canceled. Claims 35 and 36 have been added. Claims 31-32 and 34-36 are pending and currently under examination.

Information Disclosure Statement

The Information Disclosure Statements filed on 9-28-200 and 11-6-200 are acknowledged. Initialed copies are attached hereto. It should be noted that not all of the cited references were available and hence the unavailable references were not considered. Said references will be considered as they become available.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: ,
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Said claim is rendered vague and indefinite by the use of the term "active Clostridial neurotoxin". It is unclear to what specific "process" Applicant is referring to with said term. Since said term is not explicitly defined in the specification, it is impossible to determine the metes and bounds of the claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31 and 34-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 6 and 8-9 of U.S. Patent No. 6,203,794. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a composition comprising **any** Clostridial neurotoxin.(claim 31) joined to a drug wherein the drug can be an intracellular acting drug generally (claim 34) or a protein synthesis toxin, an inhibitor of neurotransmitter release, a neuronal calcium channel blocker, a ribozyme or an oligonucleotide specifically (claims 34 and 36). Moreover, the specific toxin can be tetanus toxin, botulinum toxin A, botulinum toxin B, botulinum toxin C, botulinum toxin D, botulinum toxin E, botulinum toxin F or botulinum toxin G (claim 35). The claims of U.S. Patent No. 6,203,794 are drawn to a composition comprising an inactive Clostridial neurotoxin (claim 1) joined to a drug wherein the drug can be an active ingredient for the treatment of botulism or tetanus, generally(claim 8) or a protein synthesis toxin, an inhibitor of neurotransmitter release, a neuronal calcium channel blocker, a ribozyme or an oligonucleotide specifically (claims 6 and 9). Moreover, the specific toxin can be tetanus toxin, botulinum toxin A, botulinum toxin B, botulinum toxin C, botulinum toxin D, botulinum toxin E, botulinum toxin F or botulinum toxin G (claim 2). Consequently, the claims of U.S. Patent No. 6,203,794 are drawn to a specific embodiment of the genus recited in the instant claims and as such render the instant claims obvious.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The instant claims are drawn to a composition comprising **any** Clostridial neurotoxin.(claim 31) joined to a drug wherein the drug can be an intracellular acting drug generally (claim 34) or a protein synthesis toxin, an inhibitor of neurotransmitter release, a neuronal calcium channel blocker, a ribozyme or an oligonucleotide specifically (claims 34 and 36). Moreover, the specific toxin can be tetanus toxin, botulinum toxin A, botulinum toxin B, botulinum toxin C, botulinum toxin D, botulinum toxin E, botulinum toxin F or botulinum toxin G (claim 35).

Claims 31-32 and 34-36 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bizzini (U.S. Patent 4,594,336 -- IDS).

Bizzini teaches a composition comprising a tetanus toxin bound to a thiol group and that said composition could be used to transport agents (medicines) to the central nervous system (see column 2, lines 56-60). Moreover, Bizzini teaches that said medicines could be transported into the nervous system via said medicine being bound to the thioliated tetanus toxin (see column 6, lines 1-40). Consequently, Bizzini anticipates the limitations of claims 31-32 and 35. Bizzini differs from the instant claims in that he does not explicitly disclose the "medicines" recited in claims 34 and 36. However, since Bizzini discloses "Medicine is intended to designate according to the invention any substance having pharmacological properties, such as pharmacological agents, chemotherapeutic agents and the like". Consequently, the specific limitations recited in claims 34 and 36 constitute obvious variations of the compositions disclosed by Bizzini. Moreover, since Bizzini et al. does not explicitly disclose the toxin used in "inactive", it is deemed, in absence of evidence to the contrary, to be active.

Claims 31-32 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Arnon (U.S. Patent 5,562,907 -- IDS).

Arnon discloses "recombinant toxins" comprising a botulinum neurotoxins and antibodies (see column 13, lines 1-25) and optionally cation-channel blocking agents (see column 14, lines 57-67). It should be noted that the antibodies are deemed to be "drugs" since they are used to prevent unwanted side-effects to the neurotoxin (see column 13, lines 35-55).

Moreover, since Arnon does not explicitly disclose the toxin used in "inactive", it is deemed, in absence of evidence to the contrary, to be active.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
June 7, 2005